K130430

MAY 2 3 2013

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stryker

Instruments

510(k) Summary

1. Contact Details

Stryker Instruments
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Christina McKee
Christina.McKee@Stryker.com

February 13, 2013

2. Device Name

Trade Name: Stryker Inflatable Vertebral Augmentation System (iVAS)

Common Name: Inflatable Bone Tamp

Classification Name:
Arthroscope
Cement, Bone, Vertebroplasty

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K113477	HRX NDN	Stryker® iVAS 20mm (10 Gauge) Balloon Catheter	Stryker Instruments
K103807	HRX NDN	Stryker® iVAS 10mm (10 Gauge) Balloon Catheter	Stryker Instruments
K093419	HRX NDN	Stryker® iVAS 15mm (10 Gauge) Balloon Catheter	Stryker Instruments

4. Device Description

The Stryker® iVAS balloon catheter is a bone tamp with an inflatable component (balloon) at the distal end. The balloon is inflated to create a void within the vertebral body.

5. Intended Use/Indications for use

The Stryker iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss® Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

6. Substantial Equivalence Comparison

The Stryker® iVAS 11 Gauge Balloon Catheter has the same intended use/indications for use as the predicate Stryker® iVAS 10 Gauge Balloon Catheter.

Although the device incorporates modifications to the balloon wall thickness, the spiral cut on the stainless steel catheter tube, and the color of the proximal reflow and luer hub, the modifications do not alter the intended use, indications for use, or the fundamental scientific technology of the predicate devices.

Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971. Stryker has determined that the modifications to the predicate device raise no new questions of safety or effectiveness.

7. Non-clinical Testing

The Stryker® iVAS balloon catheter meets the specification and performance characteristics and are substantially equivalent to the predicate devices. The modified device is not technologically different than the predicate device.

8. Clinical Testing

No clinical testing was deemed necessary for this 510(k).

9. Conclusions

The Stryker® iVAS (10mm and 15mm) 11 Gauge balloon catheters are substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the previously cleared Stryker® iVAS Balloon Catheters and the Kyphx Xpander Inflatable Bone Tamp. The products have the same fundamental scientific technology, basic design, functional characteristics and the same clinical applications. The Stryker® iVAS balloon catheter does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker® (10mm and 15mm) 11 Gauge iVAS balloon catheters are equivalent to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
% Ms. Christina McKee
Regulatory Affairs Associate Analyst
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Letter dated: May 23, 2013

Re: K130430
Trade/Device Name: Stryker® Inflatable Vertebral Augmentation System (iVAS)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: April 15, 2013
Received: April 19, 2013

Dear Ms. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: Stryker Inflatable Vertebral Augmentation System (iVAS)

Indications for Use

The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Prescription Use ____X____ and/or Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130430